

Remarks/Arguments:

Claims 30-38 are presented hereby in place of claims 19-29, cancelled hereby without prejudice or disclaimer. Entry of claims 30-38 after final rejection is requested for reasons set forth among the instant remarks.

Claims 30-38 contain the subject matter of claims 19-25 and 28-30. Claim 30 corresponds to claim 19 revised to more clearly define the invention and, so, resolve the issue raised in the rejection under 35 USC 112, ¶2, as explained below. Claims 31-38, which are directly or indirectly dependent on new claim 30, contain subject matter in claims 21-25 and 28-30, as explained throughout the following remarks.

The rejection of claim 26 under 35 USC 101 is rendered moot by cancellation of the rejected claim, hereby.

Claims 19, 23, 26, 28, and 29 were rejected under 35 USC 112, ¶2, for allegedly being indefinite. Reconsideration is requested in view of the changes in claim language effected, hereby, in conjunction with the following remarks.

According to the statement of rejection, claim 19 allegedly "is indefinite because it is unclear whether the claim is drawn to a peptide sequence with open (comprising) or closed (consisting) language." (Office Action, page 8.) The statement of rejection is mistaken.

First of all, it is applicants' sole prerogative to define the claims. *In re Pilkington*, 162 USPQ 145, 148 (CCPA 1969). There is no requirement in the Statute or Regulations that a patent applicant must use "comprising" or "consisting." Satisfaction of Section 112, paragraph 2 requires only that

one skilled in the art would not be confused as to the subject matter circumscribed by the claim language. *In re Kroekel*, 183 USPQ 610 (CCPA 1974).

With respect to claim 19, one skilled in the art would not be confused as to the subject matter circumscribed, thereby, i.e., the "purified peptide sequence" precisely identified, which corresponds to "SEQ ID NO: 10." SEQ ID NO: 10 as described in the instant specification and Sequence Listing, contains exactly 26 amino acid residues, no more, no less. The amino acid sequence recited in claim 19 contains exactly the same sequence of 26 amino acid residues, no more, no less, as that identified with SEQ ID NO 10 in the instant specification and sequence listing. Therefore, one skilled in the art would readily understand that claim 19 defines the expressly recited sequence of 26 amino acid residues, no more, no less. The PTO cannot read open-ended language such as "comprising" into the claim. [Citation], construe the claim as if it contained the imputed language, and find the claim indefinite as so construed.

Notwithstanding, the impropriety of finding claim 19 indefinite under Section 112, paragraph 2, applicants have amended claim 19, hereby, to include the transitional phrase "consisting of" in order to expedite prosecution.

Claims 23, 26, 28, and 29 are indefinite, according to the statement of rejection, for allegedly containing improper Markush groups. As suggested in the Office Action, the present, replacement claims recite "wherein" and "selected from the group consisting of" in order to overcome the rejection. Applicants wish to thank the examiner for kindly suggesting claim language that overcomes the rejection.

The rejection under Section 112, paragraph 2, as applied against claim 26 is rendered moot by the cancellation of claim 26, hereby.

Claims 19-27 were rejected under 35 USC 112, ¶1, for allegedly lacking enablement. Reconsideration is requested in view of the changes in the claims effected, hereby, in conjunction with the following remarks.

According to the statement of rejection, the specification is "enabling for: a method for administering a medicament comprising SEQ ID NO: 10 and auxiliary agents to promote cell proliferation of osteoblasts" (Office Action, page 6). Also according to the statement of rejection, claims 21 and 24 allegedly lack enablement "for a method of preventing or stopping [i.e., *prophylaxis of*] a degenerative or metabolic bone disease"; and, furthermore, allegedly because "the specification has not taught how to treat degenerative or metabolic bone disease" (Office Action, page 7). No other claims or claimed subject matter is identified in the statement of rejection.

With respect to rejected claims 19-23, they are not *method* claims; claims 19-23 cover a "peptide" and a "medicament" of the instant invention. The subject matter of claims 19-23 includes neither "preventing or stopping a degenerative or metabolic bone disease" nor "how to treat degenerative or metabolic bone disease."

Accordingly, "peptide" and "medicament" claims 19-23 must be enabled under §112, ¶1, as to their usefulness, but usefulness is not required for "all objectives stated in the specification. . . . An invention need not be the best way or the only way to accomplish a certain result, and it need only be useful to some extent and in certain applications." *Carl Zeiss Stiftung v. Renishaw plc*, 20

USPQ1094, 1100 (Fed. Cir. 1991). Total incapacity, i.e., incapacity with respect to all uses of the invention described in the specification, is necessary to demonstrate lack of enablement with respect to the invention claimed. *Tol-O-Matic Inc. v. Proma Produkt-Und Marketing Gesellschaft m.b.H.*, 20 USPQ2d 1332, 1338 (Fed. Cir. 1991).

In the present case, *in vivo* test results are reported in the specification in connection with animal testing. Successful test results in an animal model can be indicative successful results in the treatment of humans. *In re Jolles*, 206 USPQ 885 (CPPA 1980). Accordingly, the rejection under Section 112, paragraph 1, for alleged lack of enablement as applied against "peptide" and "medicament" claims 19-23 cannot be maintained, nor can the rejection be applied against present, replacement "protein" and "medicament" claims 30-34.

As applied against method claims 24-27, the rejection under Section 112, paragraph 1, for lack of enablement cannot be maintained for, essentially, the same reasons as set forth above in connection with the same rejection as applied to the "peptide" and "medicament" claims. That is, enablement with respect to a single use in accordance with the specification and with respect to only a limited usefulness is all that is required to satisfy the requirements of enablement under §112, ¶1.

Carl Zeiss Stiftung, supra.

Additionally, none of the present, replacement, method claims 31 and 35-37 requires "preventing or stopping [i.e., *prophylaxis* of] a degenerative or metabolic bone disease," for which enablement is allegedly lacking according to the statement of rejection.

In fact, present claim 31 is a "method comprising administering the peptide according to claim 30 to a person in need thereof to promote proliferation of osteoblasts"; and, the statement of rejection (Office Action, page 6, lines 9-11) indicates that promoting the proliferation of osteoblasts by administering the peptide of SEQ ID NO: 10 is enabled by the instant specification.

What is more, the statement of rejection, explicitly, finds that the instant specification is "enabling for: a method for administering a medicament comprising SEQ ID NO: 10 and auxiliary agents to promote cell proliferation of osteoblasts" (Office Action, page 6), as indicated above; and, present claim 35 (which replaces claim 24, is a method of use, the use "comprising administering the protein [SEQ ID NO: 10] to maintain or promote bone growth in a person suffering from a degenerative or metabolic disease of the bones"; and, in accordance with the statement of rejection as contained in the Office Action mailed October 10, 2002 (which is incorporated, by reference, into the current, final Office Action), the specification is "enabling for a peptide ... consisting of SEQ ID NO: 10 ... and that said peptide has cell proliferative properties on osteoblasts and methods of administering ... SEQ ID NO: 10 to promote bone growth (Office Action mailed October 10, 2002, page 4).

Present method claim 37 is a "method comprising administering a peptide according to claim 30 to a person in need thereof to protect or promote bone formation." (Protection of ____ bones being a purpose of the presently claimed invention as set forth at page 1, lines 1-13 of the present specification."

Claims 19, 20, 28, and 29 were rejected under 35 USC 102(e) for allegedly being anticipated by US5869638 (Takeshita). Reconsideration is requested.

For anticipation under § 102 to exist, each and every claim limitation, as arranged in the claim, must be found in a single prior art reference. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 USPQ 253 (Fed. Cir. 1985). The absence from a prior art reference of a single claim limitation negates anticipation. *Kolster Speedsteel A B v. Crucible Inc.*, 230 USPQ 81 (Fed. Cir. 1986). A reference that discloses "substantially the same invention" is not an anticipation. *Jamesbury Corp.* To anticipate the claim, each claim limitation must "*identically appear*" in the reference disclosure. *Gechter v. Davidson*, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997) (*emphasis added*). To be novelty defeating, a reference must put the public in possession of the identical invention claimed. *In re Donahue*, 226 USPQ 619 (Fed. Cir. 1985).

Takeshita teaches that human OSF-4-1 encodes a protein consisting of 796 amino acids, including a signal peptide composed of 24 amino acid residues (Takeshita column 4, lines 51-54). On the other hand, in accordance with the presently claimed invention, the claimed peptide, composed of residues 26-51 ("peptide 26-51"), is not taught as part of the signal peptide.

The presently claimed peptide 26-51 is the N-terminal part of the pro-sequence of the full length hOSF-4-1 sequence, after the pre-sequence (the signal peptide) has been cleaved. Since the presently claimed peptide 26-51 was found in human plasma as a circulating peptide, it is clear that the real signal peptide is composed of residues 1-25, rather than residues 1-24 as deduced by Takeshita by data mining of the hOSF-4-1 cDNA sequence.

In the subsequent maturing process of the hOSF-4-1 molecule, the peptide 26-51 is cleaved as a pro-sequence and the mature hOSF-4-1 molecule, consisting of the five EC domains and the TM and CP domain, remains to execute the classical cadherin function as proposed by Takeshita. Takeshita also does not denominate (see, e.g., the mouse schematic of OSF-4-1 in Fig. 1) or mention any function of this pro-sequence and apparently was unable to determine the exact sequence of this pro-sequence, i.e., because the reference deduces its disclosure about the different domains of the hOSF-4-1 from data mining of the hOSF-4-1 cDNA.

In contrast to Takeshita, the instant inventors were able to correctly and precisely describe the – and C-terminal amino acid residues of this pro-sequence (peptide) 26-51. By analyzing the circulating peptide, as correctly sequenced, the instant inventors were able to associate a biological function, i.e., promoting cell proliferation, for the peptide 26-51. Thus, the presently claimed invention is based on real, biochemical data obtained *in vivo*, not merely that obtained *in vitro*.

Moreover, Takeshita is patentably distinguished by the present claims limited to "consisting of" the recited sequence. When used as the "transitional phrase" of a claim, "consisting of" renders the claim closed to any non-recited elements. *In re Janakirma-Rao*, 135 USPQ 893 (CCPA 1963); *Ex parte Davis*, 80 USPQ 448 (POBdApp 1948).

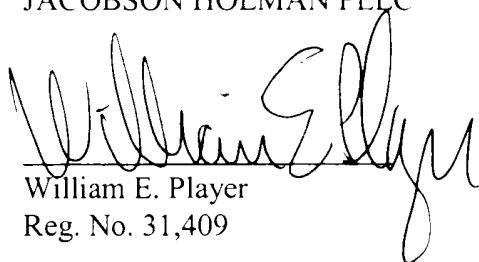
Attorney Docket No. P65315US0
Application No.: 09/509,559

Favorable action is requested.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By



William E. Player
Reg. No. 31,409

400 Seventh Street, NW
The Jenifer Building
Washington, D.C. 20004
Tel. (202) 638-6666
Fax (202) 393-5350
Date: October 2, 2003
WEP/bap

R:\rthomas 2003 OCTOBER P65315US0 and & eot wpd